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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,683	03/20/2000	MICHAEL ANTHONY CAWTHORNE	00537/163002	7045

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/423,683	CAWTHORNE ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,34,35,38,40,41,44,46,47,50,52 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,34,35,38,40,41,44,46,47,50,52 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *23*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEGMENT OF AMENDMENT, REMARKS, RCE, IDS, STATUS OF THE APPLICATION AND CLAIMS

1. The communication filed 2/2/04 is acknowledged, entered and considered. Applicant's request for regular continued prosecution (RCE) is noted. However, the criteria for filing RCE are: a) the RCE should be submitted after a final rejection, b) the submission my be a previously filed amendments(s) after final rejection and/or an amendment accompanying the RCE as set forth in 37 CFR 1.114, c) a submission may include an information disclosure statement, an amendment to the written description, claims, or drawings, new arguments, or new evidence in support of patentability, and d) if a reply to the Office action is outstanding the submission must meet the reply requirements of 37 CFR 1.111.

The request for filing RCE has not met the required criteria above. The request for filing RCE is untimely.

2. The amendment, remarks and information disclosure statement (IDS) and FormPTO-1449 filed 2/2/04 are acknowledged, entered and considered. In view of Applicant's request, claims 32, 38, 44 and 50 have been amended and claims 1, 6, 8, 18, 33, 36-37, 39, 42-43, 45, 48-49, 51 and 54-55 have been canceled. Claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53 are now pending in the application.

The rejections under 35 U.S.C. 112, second paragraph, 35 U.S.C. 102(b) and 35 U.S.C. 103(a) over the prior art of record are withdrawn in view of Applicant's amendment, remarks and cancellation of the claims.

HEADING FOR NONSTATUTORY DOUBLE PATENTING

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

REJECTION OF OBVIOUSNESS-TYPE DOUBLE PATENTING

4. Claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53 as amended remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 3, 5-8, 10-13 and 15 of U.S. Patent No. 6,004,928. Although the conflicting claims are not identical, they are not patentably distinct from

each other because the instantly claimed invention (Serial No. 09/423,683) as amended and currently claimed in claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53 is directed to a pharmaceutical composition comprising a therapeutically effective amount of a type-5 receptor selective somatostatin agonist (SSTR-5 agonist) effective for the treatment of hyperlipidemia in a patient, or to reduce triacylglycerol, glycerol and cholesterol levels in the blood of said patient as claimed in claims 2, 3, 5-8, 10-13 and 15 of '928 patent. Although, claims 2, 3, 5-8, 10-13 and 15 of '928 patent is directed to method claims; however, the specific compositions claimed in claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53 in the instant application is the same compositions used in method claims 2, 3, 5-8, 10-13 and 15 of '928 patent. Thus, from the claims, it is an obvious variation to select or use either the composition claims or method claims separately or in combination because in both situations (i.e., the compositions claimed in claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53 are used in the method of claims 2, 3, 5-8, 10-13 and 15 of '928 patent) the same compositions are used for the same purpose. Therefore, both inventions are an obvious variation of the other since the instantly claimed invention claims pharmaceutical compositions (i.e., claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53) which are claimed in method of treatment claims of 2, 3, 5-8, 10-13 and 15 of '928 paten for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other.

ARGUMENTS ARE NOT PERSUASIVE

5. The rejection under the judicially created doctrine of obviousness-type double patenting is maintained for the reasons of record for currently pending claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53. It is noted that Applicant has canceled method claims 1, 6, 8, and 18 as well as composition claims 33, 36-37, 39, 42-43, 45, 48-49, 51 and 54-55. Also, it is noted that Applicant has amended independent claims 32, 38, 44 and 50 to recite a pharmaceutical composition comprising a somatostatin type-5 receptor selective agonist. Since composition claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53 have been rejected previously under the judicially created doctrine of obviousness-type double patenting is modified as following. This is not a new rejection since Applicant has amended independent claims 32, 38, 44 and 50 by incorporating the limitations of canceled claims 33, 39, 45 and 51, respectively and because of the amendment, a new ground of modification is necessitated. Thus, this does not preclude the Examiner from making this Office action Final and the Examiner will respond to Applicant's arguments as they apply to the rejection set forth.

6. The rejection of claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53 as amended under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 3, 5-8, 10-13 and 15 of U.S. Patent No. 6,004,928.

Applicant's arguments filed 2/2/04 have been fully considered but they are not persuasive. Applicant has argued that claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53 are drawn to a pharmaceutical composition whereas the claims of U.S. Patent No. 6,004,928 are drawn to a method of treatment, and as such the claims may be

pursued in separate patent applications if, *inter alia*, a process of using a product as claimed can be practiced with another materially different product is noted. However, as stated above, the specific compositions claimed in claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53 in the instant application is the same compositions used in method claims 2, 3, 5-8, 10-13 and 15 of '928 patent. Thus, from the claims, it is an obvious variation to select or use either the composition claims or method claims separately or in combination because in both situations (i.e., the compositions claimed in claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53 are used in the method of claims 2, 3, 5-8, 10-13 and 15 of '928 patent) the same compositions are used for the same purpose. Therefore, both inventions are an obvious variation of the other since the instantly claimed invention (i.e., claim 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53) claims a pharmaceutical composition comprising a therapeutically effective amount of a type-5 receptor selective somatostatin agonist (SSTR-5 agonist) effective for the treatment of hyperlipidemia in a patient, or to reduce triacylglycerol, glycerol and cholesterol levels in the blood of said patient, which are claimed in method of treatment claims of 2, 3, 5-8, 10-13 and 15 of '928 paten for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other. Further, Applicant's request that the rejection be held in abeyance until such time as an allowable set of claims has been achieved is noted. However, since there is no allowable set of claims are currently presented, the rejection is maintained for the reasons set forth above.

Applicant's amendment, remarks and cancellation of claims with respect to the rejection under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) over the prior art of record have been considered but deemed to be moot in view of the new ground of rejections necessitated by Applicant's amendment.

NEW GROUNDS OF REJECTIONS

CLAIMS REJECTION-35 U.S.C. § 103(a)

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32, 34-35, 38, 40-41, 44, 46-47, 50, and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/35950 taken with Moller et al. (Clin. Science, Vol. 75, pp. 345-350, 1988).

The primary reference of WO 96/35950 discloses a pharmaceutical composition comprising ligands selective for somatostatin type-5 receptor agonist (SSTR-5), which is effective in treating hyperamylinemia in a patient (see e.g. Summary of the Invention). On page 4, lines 26-37, the reference defines SSTR-5 agonist by stating what is meant by "SSTR-5 agonist" or, in the claims, "a somatostatin type-5 receptor agonist" is a compound which (i) is more selective for SSTR-5 than for SSTR-2, i.e., its K_i for SSTR-5 is lower than that for SSTR-2 (i.e., has a higher binding affinity); and (ii) inhibits the release of amylin from pancreas cells induced by an amylin release stimulator. On pages 5-6, the reference discloses the effective amount of the pharmaceutical formulation of the compound and on page 7, the reference states that a preferred SSTR-5 agonist has at least 3 times less than its K_i for SSTR-2 receptor, and more preferred SSTR-5 agonist has10 times less than its K_i for SSTR-2 receptor, and as such meets the limitations of claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53.

The primary reference differs from claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53 in not teaching the use of pharmaceutical composition for treating hyperlipidemia or lowering triacylglycerols, glycerols and cholesterols in the blood of a patient. However, the secondary reference of Moller et al. discloses a pharmaceutical composition for treatment of hyperlipidemia or lowering triacyglycerols or glycerols or cholesterol in the blood of a patient comprising an effective amount of a somatostatin

type-5 receptor agonist (SSTR-5 agonist) as directed to claims 32, 38, 44 and 50 (See e.g., pages 345, 347, 348, Figures 4 and 5).

Although, the primary reference of WO 96/35950 discloses a pharmaceutical composition for treatment of hyperamylinemia comprising an effective amount of a somatostatin type-5 receptor selective agonist (SSTR-5 agonist); however, the secondary reference of Moller et al. discloses a pharmaceutical composition for treatment of hyperlipidemia or lowering triacyglycerols or glycerols or cholesterol in the blood of a patient comprising an effective amount of a somatostatin type-5 receptor agonist (SSTR-5 agonist). Nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d 875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada,* 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969).

Further, Applicant's claims are directed to somatostatin type-5 receptor selective agonist, however, the term "comprising" would not exclude other somatostatins. Thus, the combined teachings of the prior art clearly discloses the use of a pharmaceutical composition comprising a therapeutically effective amount of a somatostatin type-5 receptor selective agonist, wherein said therapeutically effective amount is an amount that is effective for the treatment of hyperlipidemia or to reduce triacylglycerole, glycerol and cholesterol levels in the blood of said patient as claimed in claims 32, 34-35, 38, 40-41, 44, 46-47, 50 and 52-53.

Therefore, in view of the above and in view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated at the time the invention was made to employ a pharmaceutical composition comprising a therapeutically effective amount of somatostatin type-5 receptor selective agonist to treat hyperlipidemia or to reduce triacylglycerol, glycerol and cholesterol levels in the blood of a patient. Thus, it is made obvious by the combined teachings of the prior art since the instant invention's methods of using of a compound with a Ki less than 5 nM for the somatostatin type-5 to treat hyperlipidemia within a patient population specifically in need of treatment of such disorder; which fall within the scope of the prior art pharmaceutical composition would have been obvious to one of ordinary skill in the art, absent of sufficient objective factual evidence or unexpected results to the contrary.

APPLICANT'S ARGUMENTS ARE UNPERSUASIVE

8. Applicant has argued that Moller et al. neither teach nor suggest a composition comprising a somatostatin type-5 receptor selective agonist which may be used to lower level of lipids (claim 32), or of triacylglycerols (claim 38), or of glycerols (claim 44), or of cholesterol (claim 50). Further, Applicant argues that somatostatin analog utilized by Moller et al. is not a SSTR-5 selective analog and has no effect on observed cholesterol levels is unpersuasive. It is noted that Applicant has canceled method claims 1, 6, 8, and 18 as well as composition claims 33, 36-37, 39, 42-43, 45, 48-49, 51 and 54-55. Also, it is noted that Applicant has amended independent claims 32, 38, 44 and 50 to recite a pharmaceutical composition comprising a somatostatin type-5 receptor selective agonist. The reference of Moller et al. discloses a pharmaceutical composition for treatment of hyperlipidemia or lowering triacyglycerols or glycerols or cholesterol in the blood of a patient comprising an effective amount of a somatostatin type-5 receptor agonist (SSTR-5 agonist).

With respect to Applicant's assertion that somatostatin taught by Miller et al. is not SSTR-5 selective agonist and has no effect on observed cholesterol levels is unpersuasive. Contrary to Applicant's assertion, the claims were not rejected in the previous Office action on the limitations of "SSTR-5 selective agonist" as currently amended. Rather, the claims were rejected on the limitations of "SSTR-5 agonist" which was taught by the prior art of Moller et al. Further, the claims as amended are directed to pharmaceutical composition comprising a therapeutically effective amount of

a somatostatin type-5 receptor selective agonist, however, the term "comprising" would not exclude other somatostatins.

In regard to Applicant's argument that the somatostatin of Moller et al. has no effect on observed cholesterol levels is not persuasive because the instantly claimed invention is directed to composition claims and **not** to method of use claims as argued by Applicant. Although, the reference of Moller et al. discloses a pharmaceutical composition for treatment of hyperlipidemia or lowering triacyglycerols or glycerols or cholesterol in the blood of a patient comprising an effective amount of a somatostatin type-5 receptor agonist (SSTR-5 agonist). Nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art as discussed above.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 34, 35, 40, 41, 46, 47, 52 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34, 35, 40, 41, 46, 47, 52 and 53 recite the limitations "said somatostatin type-5 receptor agonist" in lines 2 and 3 of the above recited claims. The amendatory "selective" is missing. Please see claims 32, 38, 44 and 50 from which claims 34, 35, 40, 41, 46, 47, 52 and 53 depend.

SUGGESTION

10. It would be advisable if Applicant considers amendment of the claims to recite ".....agonist selective for somatostatin type-5 receptor....".

ACTION IS FINAL, NECESSITATED BY AMENDMENT

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CONCLUSION AND FUTURE CORRESPONDENCE

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272-0955. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Mohamed/AAM
May 10, 2004